

Patent Application Serial No. 09/740,191

IN THE CLAIMS:

Please amend claims 12 -23 as set forth below. Applicants note that all claims currently pending in the application are shown below for clarity.

102 Claim 12 (Currently Amended): A sustained-release, ~~liquid formulation~~ dosage form comprising:
~~a capsule comprising an expandable layer which expands upon contact with fluid;~~
~~and~~
a self-emulsifying drug formulation contained within a capsule, wherein the dosage form is configured to expel the self-emulsifying drug formulation from the capsule at a sustained rate after introduction of the dosage form to an environment of operation.

20 Claim 13 (Currently Amended): The dosage form of claim 12, ~~wherein the further comprising an expandable layer comprises~~ formed of an osmotic hydrogel, an osmotically effective solute, and a hydroxyalkylcellulose, wherein the expandable layer is positioned such that the self-emulsifying drug formulation can be expelled from the capsule upon expansion of the expandable layer.

Claim 14 (Currently Amended): The dosage form of claim 13, ~~further comprising 12,~~ wherein the capsule comprises an inner surface and an outer surface and a semipermeable membrane surrounding the capsule and having an is formed over at least a portion of the outer surface of the capsule, the semipermeable membrane being created such that an exit orifice is formed or formable therein.

Claim 15 (Currently Amended): The dosage form of claim 14, wherein the semipermeable membrane comprises a cellulose acetate and a polyethylene glycol.

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102 Claim 16 (Currently Amended): The dosage form of claim 14 12, wherein the self-emulsifying drug formulation comprises a drug selected from the group consisting of a peptide, protein, protein anabolic hormone, growth promoting hormone, endocrine system hormone, porcine growth promoting hormone, bovine growth promoting hormone, equine growth promoting hormone, human growth promoting hormone, hormone derived from a pituitary gland, hormone derived from a hypothalamus gland, recombinant DNA, somatotropin, gonadotropic releasing hormone, follicle stimulating hormone, luteinizing hormone, LH-RH, insulin, colchicine, chorionic gonadotropin, oxytocin, vasopressin, desmopressin, adrenocorticotrophic hormone, prolactin, bypressin, thyroid stimulating hormone, secretin, pancreozymin, enkephalin and glucagon.

cont. Claim 17 (Currently Amended): The dosage form of claim 14 12, wherein the self-emulsifying drug formulation comprises a surfactant selected from the group consisting of polyoxyethylenated castor oil comprising 9 moles to 52 moles of ethylene oxide, polyoxyethylenated sorbitan monopalmitate comprising 20 moles of ethylene oxide, polyoxyethylenated sorbitan monostearate comprising 20 moles of ethylene oxide, polyoxyethylenated sorbitan monostearate comprising 4 moles of ethylene oxide, polyoxyethylenated sorbitan tristearate comprising 20 moles of ethylene oxide, polyoxyethylenated sorbitan monostearate comprising 20 moles of ethylene oxide, polyoxyethylenated sorbitan trioleate comprising 20 moles of ethylene oxide, polyoxyethylenated stearic acid comprising 8 moles of ethylene oxide, polyoxyethylene lauryl ether, polyoxyethylenated stearic acid comprising 40 moles to 50 moles of ethylene oxide, polyoxyethylenated stearic acid comprising 50 moles of ethylene oxide, polyoxyethylenated stearyl alcohol comprising 2 moles of ethylene oxide, and polyoxyethylenated oleyl alcohol comprising 2 moles of ethylene oxide.

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Claim 18 (Currently Amended): A sustained-release, ~~liquid formulation~~ dosage form comprising a ~~capsule comprising an expandable layer which expands upon contact with fluid;~~ and:

a self-emulsifying drug formulation comprising a drug, a surfactant, and an oil selected from the group consisting of a vegetable, mineral, animal and marine oil, an ester of an unsaturated fatty acid, a monoglyceride, a diglyceride, a triglyceride, an acetylated glyceride, olein, palmitin, stearin, lauric acid hexylester, oleic acid, oleylester, glycolized ethoxylated glycerides of oils, fatty acids comprising 13 molecules of ethyleneoxide, and oleic acid decylester; and

a capsule containing the self-emulsifying formulation, wherein the dosage form is configured to expel the self-emulsifying drug formulation from the capsule at a sustained rate after introduction of the dosage form to an environment of operation.

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Claim 19 (Currently Amended): The dosage form of claim 18, ~~wherein the further comprising an expandable layer comprises~~ formed of an osmotic hydrogel, an osmotically effective solute, and a hydroxyalkylcellulose, wherein the expandable layer is positioned such that the self-emulsifying drug formulation can be expelled from the capsule upon expansion of the expandable layer.

Claim 20 (Currently Amended): The dosage form of claim ~~19 comprising~~ 18, wherein the capsule comprises an inner surface and an outer surface and a semipermeable membrane surrounding the capsule and having an is formed over at least a portion of the outer surface of the capsule, the semipermeable membrane being created such that an exit orifice is formed or formable therein.

Claim 21 (Currently Amended): The dosage form of claim 20, wherein the semipermeable membrane comprises a cellulose acetate and a polyethylene glycol.

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Claim 22 (Currently Amended): The dosage form of claim 20 18, wherein the drug is selected from the group consisting of a peptide, protein, protein anabolic hormone, growth promoting hormone, endocrine system hormone, porcine growth promoting hormone, bovine growth promoting hormone, equine growth promoting hormone, human growth promoting hormone, hormone derived from a pituitary gland, hormone derived from a hypothalamus gland, recombinant DNA, somatotropin, gonadotropic releasing hormone, follicle stimulating hormone, luteinizing hormone, LH-RH, insulin, colchicine, chorionic gonadotropin, oxytocin, vasopressin, desmopressin, adrenocorticotrophic hormone, prolactin, bypressin, thyroid stimulating hormone, secretin, pancreozymin, enkephalin and glucagon.

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Claim 23 (Currently Amended): The dosage form of claim 20 18, wherein the surfactant is selected from the group consisting of polyoxyethylenated castor oil comprising 9 moles to 52 moles of ethylene oxide, polyoxyethylenated sorbitan monopalmitate comprising 20 of ethylene oxide, polyoxyethylenated sorbitan monostearate comprising 20 moles of ethylene oxide, polyoxyethylenated sorbitan monostearate comprising 4 moles of ethylene oxide, polyoxyethylenated sorbitan tristearate comprising 20 moles of ethylene oxide, polyoxyethylenated sorbitan monostearate comprising 20 moles of ethylene oxide, polyoxyethylenated sorbitan trioleate comprising 20 moles of ethylene oxide, polyoxyethylenated stearic acid comprising 8 moles of ethylene oxide, polyoxyethylene lauryl ether, polyoxyethylenated stearic acid comprising 40 moles to 50 moles of ethylene oxide, polyoxyethylenated stearic acid comprising 50 moles of ethylene oxide, polyoxyethylenated stearyl alcohol comprising 2 moles of ethylene oxide, and polyoxyethylenated oleyl alcohol comprising 2 moles of ethylene oxide.

Claim 24 (Previously Amended): The dosage form of claim 20, wherein the semipermeable membrane comprises a thermoplastic polymer composition having a softening point of 40°C to 180°C.